JAN 3 0 2001

K002231

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510(k) SUMMARY

LF-DP Gastrointestinal and Sigmoid Fiberscope, accessories and ancillary equipment

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Section807.92.

A. Submitter's Name, Address, Phone and Fax Number

1. Manufacturer of the subject device

Name & Address of Manufacturer;	Olympus Optical Co,. Ltd. 2-3-1 Shinjuku Monolis Nishi-shinjuku Shinjuku-ku, Tokyo, 163-0914 Japan
Registration No :	810047
Address, Phone and Fax Number of R&D Department Endoscope Division	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-5177 FAX 81-426-46-5613

2 Name of Contact Person

Name :	Ms.Laura Storms-Tyler Director, Regulatory Affairs Olympus America Inc.
Address, Phone and Fax	Olympus America Inc. Two Corporate Center Drive Melville, NY 11747-3157 TEL (631)844-5688 FAX (631)844-5416

B. Device Name, Common Name

1. Device Name :	LF-DP Gastrointestinal and Sigmoid Fiberscope, accessories and ancillary equipment.
2. Common/Usual Name :	Gastrointestinal and Sigmoid Fiberscope
3. Classification Name :	21CFR 876.1500 Class II

C. Predicate Devices :

# K981543	LF-DP Tracheal Intubation Fiberscopes, accessories and ancillary equipment

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D. Summary Description of the Device

1. Summary

The subject device, the LF-DP for use in the upper and lower digestive tract, is identical to the predicate device, the LF-DP Tracheal Intubation Fiberscope. The only difference between the subject and predicate devices is the indications for use. There are no other differences in design, materials or specifications. This does not affect the safety or efficacy of the subject.

2. Design

"LF-DP Gastrointestinal and Sigmoidfiberscope" has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirements of IEC 60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-2-18.

3. Materials

There are no new patient-contacting materials.

E. Intended Use of the device

Except for expanding the intended use to include use within the upper and lower digestive, other characteristics of the Olympus LF-DP Gastrointestinal and Sigmoidfiberscope is identical to the Predicate Olympus LF-DP Tracheal Intubation.

F. Technological Characteristics

This endoscope does not have special technological characteristics, when compared to the predicate device.

G. Reason for not requiring clinical data

When compared to the predicate devices, "LF-DP Gastrointestinal and Sigmoidfiberscope" does not incorporate any significant change for safety and efficacy to the predicate device. Therefore clinical data is not necessary for its evaluation of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2001

Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K002231
Olympus LF-DP Gastrointestinal
and Sigmoid Fiberscope
Dated: December 12, 2000
Received: December 13, 2000
Regulatory Class: II
21 CFR §876.1500/Procode: 78 FDS, FCW, GCT, KOG

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K002231

510(k) Number(if known): Not assigned yet

Device Name: Olympus LF-DP Gastrointestinal and Sigmoid Fiberscope

Indications for Use:

Olympus LF−DP Gastrointestinal and Sigmoid Fiberscope, accessories and ancillary equipment are inetend for observation of the upper and lower digestive tract including esophagus, stomach, and sigmoid colon.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Carolyn Y Neuland for Dan Schultz

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K002231

(Optoinal Format 1-2-96)